

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
GAINESVILLE DIVISION**

TIBER LABORATORIES, LLC, :
Plaintiff, :
v. :
CIVIL ACTION NO.

2:07-CV-0069-RWS

HAWTHORN :
PHARMACEUTICALS, INC., :
Defendant. :

CYPRESS PHARMACEUTICAL, :
INC., :
Plaintiff, :
v. :
CIVIL ACTION NO.

2:07-CV-0092-RWS

TIBER LABORATORIES, LLC :
Defendant. :

TIBER LABORATORIES, LLC, :
Plaintiff, :
v. :
CIVIL ACTION NO.

2:07-CV-0093-RWS

CYPRESS :
PHARMACEUTICALS, INC., and :
G&S ENTERPRISES, d/b/a/ :
GREAT SOUTHERN :
LABORATORIES, :
Defendants. :

ORDER

This case comes before the Court on Tiber Laboratories, LLC's Motion
for Temporary Restraining Order [3], which the parties have recast and which

the Court construes as a Motion for Preliminary Injunction;¹ Hawthorn Pharmaceuticals, Inc.’s Motion to Transfer [6]; Hawthorn Pharmaceuticals, Inc.’s Motion to Supplement [7]; and Tiber Laboratories, LLC’s Motion to Supplement [8]. Each of the above motions are pending in Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc., No. 2:07-CV-0069-RWS (filed Jun. 18, 2007). After reviewing the record, the Court enters the following Order.

Background

The present three actions arise out of allegations of patent infringement made by Tiber Laboratories, LLC (“Tiber”).² Tiber is the assignee of Patent No. 6,979,689 (the “‘689 Patent”), which is directed to a three-ingredient pharmaceutical composition for the treatment of upper respiratory and oral pharyngeal congestion and related symptoms in pediatric patients. The ‘689 Patent teaches a composition of (i) diphenhydramine as an antihistamine, (ii) an opioid antitussive agent (such as codeine or hydrocodone), and (iii) a decongestant. Tiber was assigned the ‘689 Patent in December 2006 as a part

¹ Tiber has also moved for a temporary restraining order in Tiber Laboratories, Inc., LLC v. Cypress Pharmaceuticals, No. 2:07-CV-0093-RWS (filed initially on Feb. 21, 2007, as No. 2:07-CV-0014-RWS). As a result of the docketing rigmarole in this case, however, that Motion is no longer reflected as pending on the Court’s docket. The Court considers both of Tiber’s requests for relief in this Order.

² Tiber is the patentee in this action. Although Tiber is the defendant in Case No. 2:07-CV-0092-RWS, the Court refers to Tiber as Plaintiff throughout this order, consistent with its decision to consolidate the three actions into Case No. 2:07-CV-0069-RWS, in which Tiber is the plaintiff.

of an asset purchase of the now-defunct pharmaceutical company PediaMed Pharmaceutical, Inc. (“PediaMed”).

The events preceding this litigation and Tiber’s acquisition of the ‘689 Patent from PediaMed warrant discussion. In 2003, PediaMed developed and began distributing the prescription cold syrup “Endal-HD,” and sought to patent Endal’s three-ingredient composition of diphenhydramine, an antitussive agent, and a decongestant, as they are used to treat pediatric patients.

Shortly after PediaMed introduced Endal-HD, Defendants in this action began producing generic versions of Endal-HD. Cypress Pharmaceutical, Inc. (“Cypress”) introduced a generic form labeled “Hydro-DP” in January 2004. Hawthorn Pharmaceuticals, Inc. (“Hawthorn”), a wholly-owned subsidiary of Cypress, introduced a similar generic form of Endal-HD under the label “Dytan-HC” in 2005. Both Hydro-DP and Dytan-HC are distributed by prescription to both pediatric and adult patients.

Two years after the introduction of Endal-HD, PediaMed’s efforts before the United States Patent & Trademark Office (“PTO”) bore fruit. On December 27, 2005, the PTO issued the ‘689 Patent to PediaMed, although only after PediaMed’s financial condition had deteriorated to the point that it had ceased distributing Endal-HD.

In December of 2006, one year after the PTO issued the '689 Patent, Tiber acquired the Endal-HD product from PediaMed. As a part of this transaction, PediaMed assigned Tiber the '689 Patent. On February 6, 2007, Tiber's counsel wrote to Cypress's President, Max Draughn, to inform Cypress that Tiber had acquired the '689 Patent, and that it considered Hydro-DP an infringing product. Tiber also informed Cypress of its intention to reintroduce the Endal-HD product into the market. Discussions commenced between representatives of Tiber and Cypress, during which Mr. Gorman of Tiber proposed a potential licensing arrangement to Cypress and offered licensing terms. Cypress declined to enter into a licensing arrangement. (See Draughn Decl. ¶ 10.)

On February 20, 2007, Cypress filed an action in the Southern District of Mississippi seeking a declaration of non-infringement and invalidity as to Tiber's '689 Patent. See Cypress Pharmaceutical v. Tiber Laboratories, No. 2:07-CV-0092-RWS (filed initially on Feb. 20, 2007, as No. 3:07-CV-108-TSL-JCS (S.D. Miss.)) [hereinafter Cypress Declaratory Action]. One day later, Tiber brought an action in the Northern District of Georgia against Cypress and a producer of its Hydro-DP product, G & S Enterprises, alleging infringement. See Tiber Laboratories, Inc., LLC v. Cypress Pharmaceuticals, No. 2:07-CV-0093-RWS (filed initially on Feb. 21, 2007, as No. 2:07-CV-

0014-RWS) [hereinafter “Tiber I”]. Several months later, on June 18, 2007, Tiber brought a separate action against Hawthorn in the Northern District of Georgia accusing its Dytan-HC product. See Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc., No. 2:07-CV-0069-RWS (filed Jun. 18, 2007) [hereinafter “Tiber II”].

Because the Cypress Declaratory Action was filed first in Mississippi, this Court transferred Tiber I to the Mississippi district court to determine, under the first-filed rule, where these related actions should proceed. Shortly thereafter, the Mississippi district court concluded that it did not have personal jurisdiction over Tiber, and transferred both the Cypress Declaratory Action and Tiber I to this Court. All three actions are now proceeding in this district.

In Tiber I and Tiber II, Tiber has moved to preliminarily enjoin Cypress and Hawthorn from marketing and distributing the Hydro-DP and Dytan-HC products to pediatric patients. (See Tiber’s Emergency Motion for Temporary Restraining Order in Tiber I [Doc. 4 in No. 2:07-CV-0014-RWS]; Tiber’s Motion for Temporary Restraining Order in Tiber II [Doc. 3 in No. 2:07-CV-0069-RWS].) The Court held a hearing on August 22, 2007 on Tiber’s request for a preliminary injunction.

In its papers, Tiber initially sought a broad remedy compelling Cypress and Hawthorn to recall the accused products from the market. Nevertheless, at

the hearing held on August 22, 2007, Tiber significantly revised the remedy it seeks. While its precise contours are not fully clear, it appears that Tiber now seeks a court order compelling Cypress and Hawthorn to place labels on the accused products indicating that the accused products should not be prescribed or distributed to pediatric patients by order of court due to patent infringement. Tiber also requests an order compelling Cypress and Hawthorn to amend the listing of the Hydro-DP and Dytan-HC products in the National Drug Data File maintained by First DataBank, Inc., Medi-Span, and other similar drug database companies, to reflect that these products should not be prescribed to pediatric patients in compliance with Tiber's patent rights.

The Court now takes up Tiber's preliminary injunctive request and several other, preliminary matters.

I. Preliminary Matters

A. Consolidation

During the hearing held on Wednesday, August 22, 2007, the parties to all three actions represented to the Court that consolidation of the above three actions for purposes of discovery and preliminary relief would advance judicial efficiency and avoid unnecessary costs and delay. Accordingly, by consent of the parties, and pursuant to its discretion under Federal Rule of Civil Procedure 42(a), the Court hereby **ORDERS** that the above three cases shall be

CONSOLIDATED into the earliest filed and administratively open action, Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc., No. 2:07-CV-0069-RWS (filed Jun. 18, 2007).

B. Motion to Transfer

On June 25, 2007, Defendants moved to transfer Tiber II, No. 2:07-CV-0069-RWS, to the Southern District of Mississippi under the first-filed rule. (See Motion to Transfer [6].) This Court stayed that case pending resolution of similar issues raised before the Mississippi District Court in the other two actions. (See Order of Jun. 29, 2007 [15] at 5-6.) As stated, the Mississippi District Court has since ruled that the first-filed rule did not apply to render venue in Mississippi appropriate in either action, and has transferred those two actions to this Court. See Cypress Pharmaceutical, Inc. v. Tiber Laboratories, LLC, No. 3:07-CV-108-TSL-JCS (S.D. Miss. Jul. 19, 2007). In view of that disposition, no cause exists for transfer of this action to Mississippi, and as such, Defendants' Motion to Transfer [6] is **DENIED**.

C. Motions to Supplement

Finally, both parties have moved to supplement the record in support of their positions on Tiber's Motion for Preliminary Injunction. For good cause shown, Defendants' Motion to Supplement [7] and Plaintiff's Motion to Supplement [8] are **GRANTED**.

II. Tiber's Motion For a Preliminary Injunction

As stated, Tiber seeks a court order compelling Cypress and Hawthorn to place labels on the accused products directing that the accused products should not be prescribed or distributed to pediatric patients in accordance with Tiber's patent rights. Tiber also requests an order compelling Cypress and Hawthorn to amend the listing of the Hydro-DP and Dytan-HC products in the National Drug Data File maintained by First DataBank, Inc., Medi-Span, and other similar drug databases, to reflect that these products should not be prescribed to pediatric patients. For the reasons that follow, the Court declines to award Tiber the requested relief.

A preliminary injunction is a "drastic and extraordinary remedy that is not to be routinely granted." Nat'l Steel Car, Ld. v. Canadian Pacific Ry., Ltd., 357 F.3d 1319, 1324 (Fed. Cir. 2004) (quoting Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993)). To obtain a preliminary injunction, the moving party must demonstrate (1) a reasonable likelihood of success on the merits, (2) irreparable harm in the absence of a preliminary injunction, (3) a balance of hardships tipping in its favor, and (4) the injunction's favorable impact on the public interest. Id.

The burden is on the movant to show entitlement to a preliminary injunction. Id. "Because, irrespective of relative or public harms, a movant

must establish both a likelihood of success on the merits *and* irreparable harm the district court may deny a preliminary injunction based on the movant's failure to establish either of these two crucial factors without making additional findings respecting the other factors." Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed. Cir. 1994) (emphasis in original); see also Rosemount, Inc. v. U.S. Int'l Trade Comm'n, 910 F.2d 819, 822 (Fed. Cir. 1990) (concluding that it was not necessary to consider whether patentee had demonstrated strong likelihood of success in proving patent validity and infringement where patentee failed to establish irreparable harm and that the balance of harm tilted in its favor); Roper Corp. v. Litton Systems, Inc., 757 F.2d 1266, 1271-73 (Fed. Cir. 1985) (same); Polymer Technologies, Inc. v. Bridwell, 103 F.3d 970, 974 (Fed. Cir. 1996) (same).

After reviewing the record and considering the filings pertinent to the instant motion, the Court seriously questions whether Tiber will overcome the challenge to the validity of the '689 Patent waged by Defendants in this action. Nevertheless, the Court finds it unnecessary to conduct an inquiry into the merits because it concludes Tiber has failed to carry its burden on the remainder of the factors to be considered on a motion for preliminary injunction.

A. Irreparable Injury

Tiber contends that it is entitled to a presumption of irreparable injury, and that in any event, it has demonstrated irreparable injury in the first instance. In support of its contention, Tiber cites the harm it will suffer in losing the benefit of the exclusionary effect of the '689 patent, the "irretrievable price erosion for the patented product caused by the presence of the infringing[] product[s]," and sales it will lose in the absence of a preliminary injunction. (See Tiber's Reply Br. in Supp. of Emergency Mot. for Temporary Restraining Order [37] in Tiber 1, No. 2:07-CV-0014 at 14.) Cypress and Hawthorn respond that Tiber is not entitled to a presumption of irreparable injury in light of the Supreme Court's decision in eBay Inc. v. MercExchange, L.L.C., ___ U.S. ___, 126 S. Ct. 1837, 164 L. Ed. 2d 641 (2006), and that, in any event, any finding of irreparable injury is precluded by both Tiber's dilatory conduct in prosecuting the instant patent action and its demonstrated willingness to license the '689 Patent. For the reasons that follow, the Court agrees that Tiber's pre-litigation conduct precludes a finding of irreparable harm, regardless of whether Tiber may avail itself of a rebuttable presumption of irreparable harm.

1. *The Presumption of Irreparable Injury is not Available to Tiber.*

For more than twenty years, the Federal Circuit has applied a categorical rule in patent cases that "an injunction will issue when infringement has been

adjudged, absent a sound reason for denying it.” See, e.g., Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 1247 (Fed. Cir. 1989). This rule has rested on the notion that the principal value of a patent is its statutory right to exclude, and thus “the nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole.” Reebok Int’l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1557 (Fed. Cir. 1994). Thus, at least in years past, where the patent holder succeeded at trial in demonstrating infringement, or where the patent holder succeeded at the preliminary injunction stage in demonstrating a likelihood of success on the merits, courts applied a rebuttable presumption that the patent holder would suffer irreparable harm in the absence of injunctive relief. Id. The presumption acts “as a procedural device which place[d] the ultimate burden of production on the question of irreparable harm onto the alleged infringer,” rather than the movant. Id. at 1556 (citing Roper Corp. v. Litton Sys., Inc., 757 F.2d 1266, 1272 (Fed. Cir. 1985)).

On May 15, 2006, however, the Supreme Court issued its decision in eBay Inc. v. MercExchange, L.L.C., ____ U.S. ___, 126 S. Ct. 1837, 164 L. Ed. 2d 641 (2006), unanimously rejecting the Federal Circuit’s application of such a presumption, at least in the context of a permanent injunction. Id. at 1839-41. Reasoning that no justification existed in the Patent Act for departing from the

traditional considerations applicable to requests for equitable relief, the Court held that the traditional four-factor test for a permanent injunction “appl[ies] with equal force to disputes arising under the Patent Act.” *Id.* at 1839. Because the Federal Circuit had erroneously applied the burden-shifting presumption that an injunction would issue upon the showing of infringement, the Court vacated and remanded the case to the district court for determination of the propriety of injunctive relief under the traditional four-factor test. *Id.* at 1841.

EBay leaves no doubt concerning the legal standard for awarding a *permanent* injunction in patent cases. However, the Federal Circuit has not yet addressed whether the Supreme Court’s decision in eBay similarly undermines the Federal Circuit’s practice of presuming irreparable harm for purposes of a *preliminary* injunction in cases where the patent holder has demonstrated a likelihood of success on the merits. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 n.9 (Fed. Cir. 2006) (declining to address whether eBay precludes the application of a presumption of irreparable harm in patent cases); but cf. Abbott Labs. v. Andrx Pharm., Inc., 452 F.3d 1331, 1334 (Fed. Cir. 2006) (noting, in discussing eBay, that requests for permanent injunctions and requests preliminary injunctions are a “closely related topic,” but later stating, after citing eBay and denying preliminary injunction, that movant was “no

longer entitled to presumption of irreparable harm" because it failed to demonstrate likelihood of success on the merits).

Most district courts, however, in the wake of eBay's rejection of any specialized, categorical treatment of injunctions in patent cases, have declined to apply a presumption of irreparable harm. See, e.g., Torspo Hockey Int'l, Inc. v. Kor Hockey Ltd., 491 F. Supp. 2d 871, 881 (D. Minn. 2007) ("In light of the Supreme Court's decision in eBay, Inc. v. MercExchange, L.L.C., however, the Court finds that it may not presume that a patentee who is likely to succeed on the merits at trial will suffer irreparable harm in the absence of a preliminary injunction."); Chamberlain Group, Inc. v. Lear Corp., No. 05-C-3449, 2007 WL 1017751 (N.D. Ill. 2007 Mar. 20, 2007) (declining to apply presumption); Sun Optics, Inc. v. FGX Int'l, Inc., No. 07-137-SLR, 2007 WL 2228569, at *1 (D. Del. Aug. 2, 2007) (same); z4 Technologies, Inc. v. Microsoft Corp., 434 F. Supp. 2d 437, 440 (E.D. Tex. 2006); Paice LLC v. Toyota Motor Corp., No. 2:04-CV-211-DF, 2006 WL 2385139, at *4 (E.D. Tex. Aug. 16, 2006) (same).³ Notably, the district court on remand in eBay also concluded that the presumption did not survive eBay (albeit in the permanent injunction context), thus concluding that the burdens of both proof and production remain with the

³ But see PHG Techs. v. Timemed Labeling Sys., 2006 U.S. Dist. LEXIS 66828, at *65 (M.D. Tenn. Sep. 18, 2006) ("[H]aving established the first factor of likelihood of success on the merits PHG is entitled to a rebuttable presumption of irreparable harm.").

movant in establishing irreparable harm. MercExchange, L.L.C. v. Ebay, Inc., __ F. Supp. 2d __, 2007 WL 2172587, at *8 (E.D. Va. Jul. 27, 2007).

This Court agrees that eBay does not leave room for a presumption of irreparable injury in patent cases, whether raised at the preliminary or permanent injunction phase. The Patent Act does not provide that special rules apply to a patent holder's request for a preliminary injunction. Thus, consistent with eBay's preservation in patent cases of the traditional analysis applicable to injunctive requests, the Court concludes that the burden of proving irreparable injury rests entirely with Tiber.⁴

⁴ The Court recognizes, however, as did the district court on remand in eBay, that certain equitable considerations unique in the patent context must be accorded proper weight in determining the existence of irreparable harm in patent cases. MercExchange, 2007 WL 2172587, at *8. As that court explained:

Although a presumption of irreparable harm is inconsistent with the Supreme Court's instruction that traditional equitable principles require the plaintiff to demonstrate that it has suffered an irreparable injury, the court is not blind to the reality that the nature of the right protected by a patent, the right to exclude, will frequently result in a plaintiff successfully establishing irreparable harm in the wake of establishing validity and infringement. See eBay, 126 S.Ct. at 1841 (Roberts, C.J., concurring) (indicating that it is unsurprising that injunctive relief has been granted in the "vast majority" of patent cases since the early 19th century "given the difficulty of protecting a right to exclude through monetary remedies"). However, putting the onus on the plaintiff to prove irreparable harm is much more than an idle exercise as numerous case specific facts may weigh against the issuance of an injunction notwithstanding the nature of the patent holder's right. [Cit.] Thus . . . [an injunction] shall only issue if plaintiff carries its burden of establishing that,

Having concluded that eBay precludes an application of the presumption, the Court turns to examine whether Tiber has demonstrated that it will suffer irreparable harm in the absence of an preliminary injunction. Nevertheless, as the Court concludes below, *even if*, despite eBay, Tiber is entitled to a presumption of irreparable injury,⁵ the Court concludes that Cypress and Hawthorne have overcome that presumption by demonstrating that Tiber's pre-litigation conduct is inconsistent with a finding of irreparable harm.

2. *Tiber's Dilatory Conduct in Bringing this Action and Tiber's Offer to License the '689 Patent Preclude a Finding of Irreparable Harm.*

To establish irreparable harm, the movant must show that the injury is immediate and is not compensable by monetary damages. Even when considered under traditional equitable rules, however, the existence of a likely infringer in the market may suffice to demonstrate irreparable harm because of the "difficulty of protecting a right to exclude through monetary remedies." See eBay, 126 S. Ct. at 1841 (Roberts, C.J., concurring); see also MercExchange, 2007 WL 2172587, at *8 (discussed supra).

based on traditional equitable principles, the case specific facts warrant entry of an injunction.

Id.

⁵ Prior to eBay, where a district court declined to consider the movant's likelihood of success on the merits, it was required to afford the patent holder the presumption of irreparable harm. See Reebok Int'l Ltd., 32 F.3d at 1556.

Where the movant “unduly delayed in bringing suit,” however, “thereby negating the idea of irreparability,” a preliminary injunction should not issue. Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 974 (Fed. Cir. 1996). In T.J. Smith & Nephew Ltd. v. Consolidated Medical Equip., Inc., 821 F.2d 646, 648 (Fed. Cir. 1987), for example—a case applying the presumption of irreparable harm—the Federal Circuit found that a 15-month delay in bringing suit precluded injunctive relief. Id. Similarly, in High Tech Medical Instrumentation, Inc. v. New Image Industries, Inc., 49 F.3d 1551, 1557-58 (Fed. Cir. 1995), the Federal Circuit held that “[a]bsent a good explanation, not offered or found here, 17 months is a substantial period of delay that militates against the issuance of a preliminary injunction by demonstrating that there is no apparent urgency to the request for injunctive relief.” Id.⁶ And finally, in Nutrition 21 v. United States, 930 F.2d 867, 872 (Fed. Cir. 1991), the Federal Circuit noted that even a seven-month delay could be sufficient to negate irreparable harm. Id.

⁶ In coming to this conclusion, the court relied on several cases in the trademark and copyright contexts that found that periods of delay of one year, High Tech Med., 49 F.3d at 1557 (citing Le Sportsac, Inc. v. Dockside Research, Inc., 478 F. Supp. 602, 609 (S.D.N.Y. 1979)); nine months, id. (citing Citibank, N.A. v. Citytrust, 756 F.2d 273, 276 (2d Cir. 1985)); and seven-and-a-half months, id. (citing Gianni Cereda Fabrics, Inc. v. Bazaar Fabrics, Inc., 335 F. Supp. 278, 280 (S.D.N.Y. 1971)), sufficient to preclude a finding of irreparable harm.

The patent at issue in this case was issued on December 27, 2005. At that time, both accused products, Hydro-DP and Dytan-HC, had already been introduced in the market. Tiber, who is charged with its predecessor-assignee's dilatory conduct,⁷ brought its action against Cypress in February of 2007, over thirteen months after the '689 Patent was issued. It brought its action against Hawthorne in June of 2007, over seventeen months after the '689 Patent was issued. This delay in both cases warrants strongly against the finding of irreparable harm.

Furthermore, as the Federal Circuit has recognized, a patentee's willingness to "forgo its patent rights for compensation" by offering to licensee its patent further militates against the existence of irreparable harm. See High Tech Med. Instrumentation, 49 F.3d at 1557 (finding that patentee's "apparent willingness to grant a license" under its patent to alleged infringer was inconsistent with allegation of irreparable harm); see also T.J. Smith & Nephew Ltd., 821 F.2d at 648 (stating that licensing is "incompatible with the

⁷ Although Tiber contends that it should not be charged with the delay of its predecessor, PediaMed, the assignee of a patent must "accept the consequences of [the assignor's] dilatory conduct." Continental Coatings Corp. v. Metco, Inc., 464 F.2d 1375, 1377 & n.6 (7th Cir. 1972) (citing George J. Meyer Mfg. Co. v. Miller Mfg. Co., 24 F.2d 505, 506 (7th Cir. 1928); Rome Grader & Machinery Corp. v. J. D. Adams Mfg. Co., 135 F.2d 617, 619-620 (7th Cir. 1943); Skinner v. Aluminum Co. of America, 105 F. Supp. 635, 637 (W.D. Pa. 1952)). Tiber has cited no authority to the contrary, and has offered no legal support for its proposition that the Court should excuse its predecessor's dilatory conduct because of its financial distress.

emphasis on the right to exclude that is the basis for the presumption in a proper case"). Tiber's apparent willingness to grant a license to Cypress during its pre-litigation discussions further undercuts its suggestion that it will be irreparably harmed absent a preliminary injunction.

Finally, despite its conclusory argument to the contrary, Tiber has not demonstrated that a monetary remedy will not adequately compensate it in this case should it prove its infringement claims.

In sum, the Court concludes that the 13-month and 17-month delay in bringing its two infringement actions combined with Tiber's apparent willingness to license the '689 patent preclude a finding of irreparable harm. What is more, the Court is not convinced that a monetary remedy will not adequately compensate Tiber if it proves its infringement claims. Because, in coming to this conclusion, the Court relies solely on authority of the Federal Circuit that pre-dated the Supreme Court's decision in eBay, even accepting for purposes of the Court's analysis that Tiber is entitled to a rebuttable presumption of irreparable harm, the Court concludes that Hawthorne and Cypress have adequately rebutted that presumption. In either event, Tiber has failed to meet its "final" burden of demonstrating irreparable harm in the absence of a preliminary injunction.

B. Balance of Hardships & Public Interest Considerations

Tiber's failure to demonstrate irreparable injury alone precludes an award of preliminary injunctive relief. See Nat'l Steel Car, Ltd., 357 F.3d at 1324. Nevertheless, the Court is further convinced that injunctive relief is not warranted in this case in view of the specific remedy Tiber preliminarily requests—namely, the court-ordered labeling of Hydro-DP and Dytan-HC prescription cold medicines with a directive that such medicines are not to be prescribed to pediatric patients. In the Court's view, Tiber's request additionally fails the third and fourth elements of the preliminary injunction inquiry.

As to the third element, Tiber has failed to convince this Court that the balance of hardships tilt in its favor. It is clear that, should Tiber succeed in proving its infringement claims in this action, Tiber will have demonstrated it suffered hardship as a result of Hawthorn's and Cypress's presence in the market for pediatric cold medicines comprising the composition protected by the '689 Patent. Nevertheless, Tiber has not provided any evidence in the record concerning the nature of the hardship Hawthorn and Cypress may suffer as the result of being compelled to label the Hydro-DP and Dytan-HC products and undergo the potentially arduous process that normally accompanies labeling of pharmaceutical drugs. Because the Court has virtually no record evidence

upon which to balance the hardships wrought by the proposed injunctive relief, Tiber has failed to meet its burden in this regard.⁸

And as to the fourth element, the Court is not convinced that the public interest favors awarding the relief requested. It is indeed true that the public interest is usually “best served by enforcing patents that are likely valid and infringed.” Abbott Labs, 452 F.3d at 1358. Nevertheless, the specific remedy requested in this case raises special, overriding concerns, even if the Court assumes for purposes of its analysis that the patent-in-issue is valid and infringed. The temporary labeling of prescription medications presently in use by pediatric patients with a message discouraging their use or dispensation may have the unintended consequence of confusing—or worse yet, alarming—pediatric patients who have used these medications and their parents and doctors. Hydro-DP has been available and prescribed to pediatric patients

⁸ As previously stated, Tiber did not specify the limited nature of the remedy it was seeking until the day of the Court’s hearing on this matter, on August 22, 2007. Tiber filed its original motion for a temporary restraining order on February 21, 2007 in Tiber I. Thus, six months passed between the time Tiber filed its Motion and the time it specifically defined the nature of the relief it sought in that motion. Despite apparently ample opportunity to do so, Tiber did not brief or otherwise provide Hawthorne or Cypress advance notice of its amended request for relief. Since Hawthorne and Cypress have not been afforded any formal opportunity to respond to the specific relief requested, any blame for the absence of evidence concerning the hardships Hawthorne and Cypress would suffer as a result of granting the specialized relief Tiber requests does not rest with Hawthorne and Cypress.

Rather, in the Court’s view, Tiber’s apparent lack of urgency in detailing the nature of the preliminary relief it has requested further undercuts Tiber’s case for injunctive relief and is at odds with a finding of irreparable harm.

for over three-and-a-half years, and Dytan-HC for approximately two years. In the Court's view, the public interest favors maintaining the *status quo* in the supply of those medications to pediatric patients, and weighs strongly against disrupting that supply and potentially misinforming pharmaceutical consumers concerning their use of prescription medication. Without specific evidence in the record alleviating these concerns, the Court declines to award the relief requested.

In sum, the Court concludes that Tiber has failed to demonstrate that it is entitled to preliminary injunctive relief. Accordingly, Tiber's Motion for a Temporary Restraining Order, which this Court construes as a Motion for a Preliminary Injunction, is **DENIED**.

Conclusion

For the foregoing reasons, the Court hereby **ORDERS** that the above three cases shall be **CONSOLIDATED** for present purposes into the earliest filed and currently pending action, Tiber Laboratories, LLC v. Hawthorn Pharmaceuticals, Inc., No. 2:07-CV-0069-RWS (filed Jun. 18, 2007). Tiber Laboratories, LLC's Motion for Temporary Restraining Order [3], which the parties have recast and which the Court construes as a Motion for Preliminary Injunction, is **DENIED**. Hawthorn Pharmaceuticals, Inc.'s Motion to Transfer [6] is **DENIED**. Hawthorn Pharmaceuticals, Inc.'s Motion to Supplement [7] is

GRANTED. Tiber Laboratories, LLC's Motion to Supplement [8] is

GRANTED.

SO ORDERED this 11th day of September, 2007.


RICHARD W. STORY
UNITED STATES DISTRICT JUDGE